

### **REMARKS**

Currently claims 1-12 are pending. In this Amendment, Claim 1 has been amended for reasons set forth below. No new matter has been added.

Basis for the amendment of claim 1 is found throughout the application as published (10/276,932), in particular at;

- Page 20, line 19 – page 28, line 16, which details the creation of datasets comprising predetermined data relating to the at least one physical parameter of the airway defined by the throat of the at least one other patient.
- Page 28, line 21 – page 31, line 31, which details the method of predicting the tendency of inhaled particles to deposit within the airway of a first, new patient, with reference to the earlier created database.

Applicant acknowledges the examiner's finding that claim 1 as filed is novel over the prior art of Sexton et al; US6,567,686 B2 and Czaja et al; Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996.

#### **1. Claims 1-8 and 11 are not rendered obvious by Sexton in view of Czaja et al.**

In the most recent action, Claims 1-8 and 11 were rejected under Section 103(a) as obvious by US 6,567, 686 to Sexton et al. (Sexton) in view of Czaja et al, Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105; 1996 (Czaja). Applicant respectfully traverses each and every aspect of this rejection.

Applicant respectfully submits that Sexton does not disclose a method for predicting the tendency of inhaled particles to deposit within a first patient's throat when said particles are inhaled through an airway defined by said first patient's throat, said method comprising selecting determining at least one

internal physical parameter of an said airway defined by a the first patient's throat of at least one other patient, by means of acoustic imaging of the airway defined by the first patient's throat; creating a dataset comprising pre-determined data relating to said at least one internal parameter of the airway defined by the throat of said at least one other patient, said dataset further comprising pre-determined data relating to the tendency of said inhaled particles to deposit within said at least one other patient's throat; and determining said at least one internal physical parameter of said the airway defined by said first patient's throat by means of acoustic imaging of the airway defined by said first patient's throat; and matching said at least one internal physical parameter of the airway of the first patient's throat with the a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of the at least one other patient, wherein said dataset also comprises pre-determined data relating to the tendency of said inhaled particles to deposit within said at least one other patient's throat, and said matching thereby enables prediction of the tendency for the inhaled particles to deposit within the first patient's throat.

Amended claim 1 is not unpatentable under 102(a), as Sexton fails to teach, suggest or motivate the skilled person to match at least one predetermined physical parameter from a first patient against a dataset comprising predetermined data relating to the tendency of inhaled particles to deposit within the airway of another person and thereby predict the tendency of inhaled particles to deposit within the airway of the first patient.

The Office Action asserts that Sexton teaches matching at least one internal physical parameter of the airway of the first patient's throat with a dataset comprising predetermined data relating to the corresponding internal physical parameter for the throat of at least one other patient (see Column 9, Lines 50-56),

*"This method **could be further enhanced to evaluate differences between genders, age groups**, and healthy volunteers versus patients. This new understanding of the delivery is used to establish a data base of aerosol administration establishing a criteria that can be used to optimize drug delivery to the lungs through better design of delivery 55 devices."*

Applicant respectfully asserts that the quoted passage does not teach the skilled person to match at least one predetermined physical parameter from a first patient against a dataset comprising predetermined data relating to the tendency of inhaled particles to deposit within the airway of another person. In fact, Sexton teaches the opposite approach; to use a method of monitoring the role of upper oropharyngeal and laryngeal geometry for the retention and elimination of respiratory drugs when administered by oral inhalation (see field of the invention, column 1, lines 14-18) to identify differences between patients.

Furthermore, Sexton does not teach the creation of a dataset prior to matching the at least one predetermined physical parameter, but teaches the possible evaluation of differences within the database.

Czaja does nothing to correct this deficiency in Sexton. As such, no prima facie case of obvious is established, for at least this reason.

The Office Action also asserts that said matching thereby enables prediction of the tendency for the inhaled particles to deposit within the first patient's throat (Column 12, Lines 20-32).

*Block 14 is the final stage where the information from capturing the real-time mobility of oropharyngeal and laryngeal structures during inhalation through an aerosol drug delivery system, the state of aerosol drug delivered, and the database which is obtained from the practice of this method can yield the criteria that can be used to design more efficient aerosol drug delivery to optimize the amount of the particular medicine to be delivered to the specific targets in the lung. This criteria can also be used to develop an aerosol administration procedure that is insensitive to gag and cough reflexes of the body so that aerosolized medicament exiting an aerosol generator effectively escapes filtration and swallowing mechanisms of the oropharynx.*

Applicant again, respectfully traverses this objection; There is no teaching in the cited passage, or anywhere else in Sexton, to predict the tendency of particles to deposit within the throat of a patient. Instead, the actual deposition of particles is directly measured and observed for the creation of the database; Figure 1a-1b of Sexton show a flow chart depicting the steps of the inventive method according to Sexton, from the application of

aerosolized particles to the establishment of design criteria for more efficient drug delivery. The database is created from data obtained from MRI scans of patients while inhaling an inhaled material (see in particular figure 1a, block 5 and block 9). Hence, Sexton only teaches the creation of a database, and the use of said database for the establishment of design criteria for more efficient drug delivery. Such a step does not explicitly or implicitly involve predicting the tendency of particles to deposit within a patient's throat. The only method described in Sexton for establishing design criteria comprises the assessment of a number of different inhalers, as set forth at Column 10, Lines 63-67. Such an iterative process involves comparing, directly, the measured data from a number of inhalers in use; as such, there is no mention, explicit or implicit, of any predictions based on the data gathered.

Again, Sexton fails to teach the skilled person all the steps of our claimed invention. Sexton also fails to teach, suggest or motivate modifications that would give rise to our claimed invention. Again, Czaja does nothing to correct his deficiency.

For at least the reasons set out above, claims 1 and 11 are neither anticipated nor rendered obvious by the teachings of the Sexton and Czaja references. As Claims 2-10 are dependent on claim 1 Applicant asserts that these claims are also patentable over Sexton et al and Czaja et al for the reasons mentioned above. For the same reasons as in claim 1, claim 11 is patentable and as claim 12 is dependent on claim 11, Applicant asserts that this claim is also patentable over Sexton et al and Czaja et al.

Applicant respectfully requests a withdrawal of this rejection, and reconsideration of the claims.

**2. Claims 9 and 12 are not rendered Obvious by Czajain view of Sexton, in view of Stapleton.**

Claims 9 and 12 stand rejected under 35 USC 103(a) as obvious by Czaja et al, Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol

Laryngol 105; 1996 in view of Sexton et al, US Patent 6,567,686 in view of Stapleton et al., On the Suitability of e-Turbulence Modeling for Aerosol Dispersions on the Mouth and Throat: A Comparison with Experiment; Journal of Aerosol Science; 2000, Vol. 31, No. 6, pp 739-749. Applicant respectfully traverses each and every aspect of this rejection.

For the same reason presented above in 1, Applicant asserts that Claims 9 and 12 are not obvious by Czaja in view of Sexton in view of Stapleton. Czaja fails to teach the elements of claim 1 detailed in the prior section. Stapleton does nothing to correct the deficiencies of Czaja and Sexton. Applicant respectfully requests a withdrawal of this rejection.

**3. Claim 10 is Not Obvious in view of Sexton in light of Czajain view of Zhao.**

Claim 10 stands rejected under 35 USC 103(a) as obvious by Sexton et al, US Patent 6,567,686 taken with Czaja et al, Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105; 1996 in view of Zhao et al., Measurement of upper airway movement by acoustic deflection; Annals of Biomedical Engineering; 1995, vol. 23, No. 1, pp. 85-94. Applicant respectfully traverses each and every aspect of this rejection.

As set out in 1 above, Applicant asserts that claim 10 is not obvious by Sexton taken with Czaja in view of Zhao.. Zhao does nothing to correct the deficiencies of Sexton and Czaja. Applicant respectfully requests a withdrawal of this rejection.

**4. Reply to the Office's Response to Arguments presented in Applicant's reply of September 15, 2009.**

Applicant maintains their position that the Office has erred in applying the references cited. Applicant preserves the right to respond to the Office's responses in further actions if necessary. It is felt that in the Office's response

to the previous arguments the Office has drawn arguments and conclusions from the cited references that are clearly not disclosed in the references and would not have been obvious to combine into one process. However, to expedite prosecution of this application, Applicant has revised claim 1 to further distinguish Applicant's claimed invention as presented in the arguments above.

### CONCLUSION

In light of the comments and amendments made herein, reconsideration is hereby requested. It is respectfully asserted that the specification and claims are in condition for allowance.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sect 1.16 or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,

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